NEW YORK UNIVERSITY SCHOOL OF MEDICINE

Peter D. LeRoux, M.D.
Assistant Professor
Department of Neurosurgery

530 First Avenue, New York, NY 10016
Telephone: (212) 263-8002
Facsimile: (212) 263-1680
e-mail: leroup01@popmail.med.nyu.edu
e-mail: leroux@mcns10.med.nyu.edu

July 7, 2000

Ms. Cathy Eberhar
Food and Drug Administration
Center for Biologic Evaluation and Research
1401 Rockville Pike
Suite 200N
Rockville, MD 20852-1448 HFM 42

Dear Ms. Eberhar

I understand that the FDA will hold an open public meeting to reevaluate the need to classify allograft as a medical device.

I see no reason why allograft should be reclassified as a medical device. I am concerned and dismayed that this proposed legislation will significantly impair effective patient treatment and outcome.

Allograft has been used for many years and has both an excellent clinical outcome and safety record. In my own practice, I use allograft in approximately 125 neurosurgical procedures each year. In many instances, more than one piece of allograft is used. Since starting my neurosurgical practice in September, 1995, I have not observed a single complication related to allograft. In addition, use of allograft rather than an homologous graft allows early mobilization and short hospital stays. In addition, it significantly reduces postoperative pain.

Regulations for infectious testing, donor screening and record keeping are already in place for allograft use. Further legislation will significantly hamper our ability to provide our patients with the care that they deserve.

Please feel free to call if you have any questions or concerns.

Sincerely,

Peter D. LeRoux, M.D.

PDL:ll

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MS. CATHY EBERHAR
FOOD AND DRUG ADMINISTRATION
CENTER FOR BIOLOGIC EVALUATION AND RESEARCH
1401 ROCKVILLE PIKE
SUITE 200N
ROCKVILLE, MD 20852-1448 HFM 42

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